



**Tinos L. L. C.**

2500 Brownsboro Road  
Louisville, KY 40204  
Phone/Fax (502) 896-4159

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NUTRITIONALS, HFS-450  
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May 16, 1996

Robert J. Moore, Ph.D.  
Senior Regulatory Scientist  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
U.S. Food and Drug Administration  
200 "C" Street, S.W.  
Washington, D.C. 20204

RE: Notification to FDA of a New Herbal Dietary Supplement

Dear Dr. Moore:

As per a letter from John W. Gordon of the Office of Special Nutritionals dated April 4, 1996, regarding the DSHEA requirement for manufacturers to notify the FDA no later than 30 days after first marketing a new dietary supplement, I am enclosing a sample label of our product called "Choc-Quilizer", which has been marketed as of May 1, 1996. Unfortunately, because of a printing error, part of the disclaimer was truncated. As a result, I will be printing an additional disclaimer statement which will be prominently displayed on the cap of the bottle to comply with the regulations. All subsequent labels will bear the complete disclaimer on the label proper.

Since we will be making a nutritional support statement on the label and/or labeling, we would like to notify the FDA that the clause, "...which helps control chocolate cravings" contained in the label is designed to "describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans," pursuant of section 403(r)(6) of the Act. The putative mechanism of action of this dietary supplement is to raise the craving set point of an animal, thereby decreasing normal cravings.

Thank you very much for all your help and advice you've given me.

With best regards,

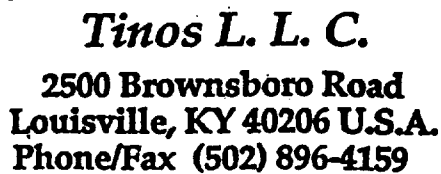
Sincerely yours,

*George A. Kargas, M.D.*  
George A. Kargas, M.D.

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**This statement  
has not been evaluated  
by the Food and Drug  
Administration.  
This product is not  
intended to diagnose,  
treat, cure, or prevent  
any disease.**